REMARKS

Applicants acknowledge the allowance of claims 1-17, 20 and 23-25. The status of claim 19 is uncertain from the summary but is presumed to be allowed since the claim has not been rejected in the detailed action.

Applicants submit the references cited in this application have already been cited and considered in other applications by the Examiner such that number of references cited should not be a burden.

In an attempt to simplify the consideration of the references cited in the IDS, Applicants have provided The Notices of References Cited (AA-AR) from related applications and the parent applications as well as the search reports from corresponding applications. Many of the references cited in Information disclosure statement were obtained from these notices and search reports.

Certain notices have not been considered on the basis that they are unpublished documents. Although not prior art, Applicants submit these documents should be considered in that they provide direction as to the source of some of the references cited in the Information Disclosure Statement.

References AC, AD and AP are notices from priority applications SN 09/425,228 and SN 09/948,915. Reference BI is the international search report for the corresponding International Application of parent application 09/425,228. Reference AU is the supplemental search report for the corresponding European application of parent application 09/425,228.

Applicants maintain all pending claims satisfy the requirements of 35 USC § 112, first paragraph, including claims 18, 21 and 22. No evidence has been presented to demonstrate the compounds of claim 1 would not be effective against any hyperproliferative disorders as claimed in claim 18 and no evidence has been presented to demonstrate the compounds of claim 1 in combination with a cytotoxic compound would be ineffective in treating or preventing any hyperproliferative disorders as claimed in claim 21. Only unsupported allegations and conclusions

regarding the art of treating hyperproliferative disorders are made to support the rejection of claims 18 and 21. Similarly, only unsupported allegations are made with respect to the methods of treating osteoporosis and inflammation claimed in claim 22. No evidence has been presented that the compounds of claim 1 are ineffective against such diseases.

The courts have placed the burden upon the PTO to provide evidence shedding doubt on the disclosure that the invention can be made and used as stated; see, e.g., *In re Marzocchi*, 439 F.2d 220, 169 U.S.P.Q. 367 (CCPA 1971) (holding that how an enablement teaching is set forth, either by use of illustrative examples or by broad terminology, is of no importance.) The disclosure must be taken as in compliance with the enablement requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein. See *In re Marzocchi*, supra. No such evidence or reason for doubting Applicants' disclosure has been provided. Only general statements and conclusions are made. In the absence of evidence to support the rejection under 35 U.S.C. § 112, first paragraph, Applicants submit this rejection should be withdrawn.

In addition, Applicants maintain the specification provides ample guidance as to how to prepare pharmaceutical compositions with the compounds of this invention and how to administer these compositions in the treatment of hyperproliferative disorders. See, e.g., pages 19-21. The specification also provides dosage ranges for the various methods of administration (see page 21-22). Given the extent of the disclosure provided, it would at most involve routine experimentation if any at all, for one of ordinary skill in the art to treat any hyperproliferative disorder with a compound of this invention. "[T]he [enablement] requirement is satisfied if, given what they [, those of ordinary skill in the art,] already know, the specification teaches those in the art enough that they can make and use the claimed invention without 'undue experimentation.'" See *Amgen v Hoechst Marion Roussel*, 314 F.2d 1313, 65 USPQ2d 1385 (Fed. Cir. 2003). Using the claimed compounds would be routine for those of ordinary skill in the art in view of applicant's disclosure.

There is no requirement that an applicant provide a working example relating to the treatment of every claimed disease to satisfy the statute. See, for example, *In re*

Angstadt, 537 F.2d at 502-03, 190 USPQ 214 (CCPA 1976) (deciding that applicants "are *not* required to disclose *every* species encompassed by their claims even in an unpredictable art"); *Utter v Higara*, 845 F.2d at 998-99, 6 USPQ2d 1714 (Fed. Cir. 1988) (holding that a specification may, within the meaning of Section 112, Para. 1, enable a broadly claimed invention without describing all species that claim encompasses). Instead, as discussed earlier, there is no requirement for any examples. See, for example, *Marzocchi*, supra, stating that how "an enabling teaching is set forth, either by use of illustrative examples or by broad terminology, is of no importance." The MPEP also agrees by stating that "compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed." See MPEP § 2164.02.

Moreover, with respect to pharmaceutical inventions, an applicant is not required to test the claimed compounds in their final use (rigorous planned and executed clinical trials..." per the Examiner). The Federal Circuit in *In re Brana*, 51 F.3d 1560, 34 USPQ 1436 (Fed. Cir. 1995), stated that:

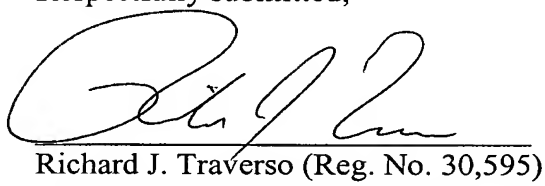
> usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful can be well before it is ready to be administered to humans. If the courts were to require Phase II testing in order to prove utility for pharmaceutical inventions, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas.

Furthermore, it is not necessary to provide a dedicated assay for a hyperproliferative disorder other than a solid cancer to enable the methods claimed. See, for example, *In re Howarth,* 654 F.2d 105, 210 U.S.P.Q. 689 (CCPA 1981) ("An inventor need not ... explain every detail since he is speaking to those skilled in the art."); *In re Gay*, 309 F.2d 769, 774, 135 U.S.P.Q 311 (CCPA 1962) ("Not every last detail is to be described, else patent specifications would turn into production specifications, which they were never intended to be.")

For the reasons discussed above, Applicants submit that they have provided more than adequate guidance (and examples) to enable the claimed invention and that the PTO has failed to meet its burden of presenting evidence to the contrary and therefore, claims 18, 21 and 22 meet the requirements of 35 U.S.C. § 112, first paragraph.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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